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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/589,084

Filing Date: October 04, 2006

Appellant(s): EITRICH ET AL.

Heribert F. Muensterer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 29, 2010 appealing from the
Office action mailed April 29, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 34-56 have been rejected in the Final Action mailed April 29, 2010; claims 1-33 have been cancelled; claims 34-56 are currently pending in the application and are under appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being

maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,231,837	STROUD	5-2001
6,391,290	FOWLER	5-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 34-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stroud *et al.* (U.S. Patent No. 6,231,837; published May 15, 2001), in view of Fowler (U.S. Patent No. 6,391,290; published May 21, 2002).

Appellants claim a method of providing human skin with a natural tanned color, wherein the method comprises applying to human skin, in an amount which is sufficient to provide a tanned color, a cosmetic or dermatological self-tanning composition which comprises dihydroxyacetone and more than 5% by weight, based on the total weight of the composition, of glycerin. The composition employed in said method is an oil-in-water emulsion, with an inner-phase droplet size larger than 500 nm or larger than 1,000 nm; and comprising x wt% glycerin, wherein $8 < x \leq 12$ wt%; and exhibits a

dihydroxyacetone:glycerin weight ratio y , wherein $1:4.5 \leq y \leq 2:3$. The composition also comprises at least one oil-in-water emulsifier that is a polyethoxylated ester of stearic acid or a polyethoxylated castor oil; or is selected from the group consisting of polyethoxylated esters of fatty acids having a chain length of 10-30 carbon atoms and a degree of ethoxylation of 5-100 and esters of saturated unbranched fatty acids with monomethoxylated glucose or polyglycerols. The at least one oil-in-water emulsifier is selected from the group consisting of sodium cetearyl sulfate, glyceryl stearate, glyceryl isostearate, glyceryl diisostearate, glyceryl oleate, glyceryl palmitate, glyceryl myristate, glyceryl lanolate, and glyceryl laurate. The composition further comprises at least one co-emulsifier that is cetearyl alcohol, or one or more other fatty alcohols having a chain length of 10-40 carbon atoms; and less than 5 wt% of at least one UV filter substance.

Stroud *et al.* disclose a method of providing human skin with a natural tanned color, wherein the method comprises applying to human skin, in an amount which is sufficient to provide a tanned color, a cosmetic or dermatological self-tanning composition which comprises dihydroxyacetone and more than 5% by weight, based on the total weight of the composition, of glycerin (Col. 1, Ins. 15-17, 21-28; Col. 2, Ins. 62-65; Col. 7, Ins. 25-28, 31-40; Col. 8, Ins. 42-45, 66-67; Col. 9, Ins. 1-5, 23-25; Col. 10, Ins. 28-38, 47-51; Col. 11, Ins. 25-26; Col. 12, Ins. 30-33; Col. 15, Ins. 30-31, 38, 42, 45-47; Col. 18, Ins. 6-7, 9; Col. 21, Ins. 24-50; Col. 22, Ins. 12-24, 48-51, 54-56; limitations of claims 34-56). The composition employed in said method is an oil-in-water emulsion comprising x wt% glycerin, wherein $8 < x \leq 12$ wt%; and can be formulated to exhibit a dihydroxyacetone:glycerin weight ratio y , wherein $1:4.5 \leq y \leq 2:3$ (Col. 7, Ins. 25-28, 31-40;

Col. 10, Ins. 28-38, 47-51; Col. 15, Ins. 30-31, 38, 42, 45-47; Col. 18, Ins. 6-7, 9; limitations of claims 35-41, 49, 51-54). The composition also comprises at least one oil-in-water emulsifier that is a polyethoxylated ester of stearic acid or a polyethoxylated castor oil; or is selected from the group consisting of polyethoxylated esters of fatty acids having a chain length of 10-30 carbon atoms and a degree of ethoxylation of 5-100 and esters of saturated unbranched fatty acids with monomethoxylated glucose or polyglycerols (Col. 21, Ins. 24-50; Col. 22, Ins. 12-24, 48-51; limitations of claims 42-45, 49). The at least one oil-in-water emulsifier is selected from the group consisting of sodium cetearyl sulfate, glyceryl stearate, glyceryl isostearate, glyceryl diisostearate, glyceryl oleate, glyceryl palmitate, glyceryl myristate, glyceryl lanolate, and glyceryl laurate (Col. 21, Ins. 24-50; Col. 22, Ins. 12-24, 48-51; limitations of claims 45, 49). The composition further comprises at least one co-emulsifier that is cetearyl alcohol, or one or more other fatty alcohols having a chain length of 10-40 carbon atoms; and at least one UV filter substance (Col. 21, Ins. 24-50; Col. 22, Ins. 12-24, 48-51; Col. 24, Ins. 6-29; limitations of claims 46-48, 50).

Fowler discloses an oil-in-water emulsion for topical application to the skin, with an inner-phase droplet size larger than 500 nm or larger than 1,000 nm; and comprising a sunless tanning agent, glycerin, at least one oil-in-water emulsifier, and at least one UV filter substance (Col. 2, Ins. 23-24, 39-43; Col. 3, Ins. 45-56; Col. 4, Ins. 15-17, 39-41, 56-58; Col. 5, Ins. 4-6, 10-12, 59-67; Col. 6, Ins. 1, 8-11; Col. 7, Ins. 24-25, 54-67; Col. 8, Ins. 1-11; limitations of claims 55-56).

Stroud *et al.* do not explicitly disclose that the method employs an oil-in-water emulsion composition with an inner-phase droplet size advantageously larger than 500 nm or larger than 1,000 nm. This deficiency is cured by the teachings of Fowler.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of the present invention to combine the respective teachings of Stroud *et al.* and Fowler to deduce applicants claimed invention.

Stroud *et al.* disclose a method for self-tanning human skin comprising topically applying to the skin an effective amount of an oil-in-water emulsion containing dihydroxyacetone, wherein the emulsion must remain on the skin for a prolonged period of time after application sufficient for the sunless-tanning Maillard reaction to result in the formation and even-distribution of the desired amount of brown pigments (Col. 1, Ins. 21-28; Col. 3, Ins. 33-43). Since Fowler teaches that an oil-in-water emulsion having individual emulsion droplets with a uniform diameter of about 1-10 μm (e.g. 1,000 to 10,000 nm) exhibits greater stability, and imparts a desirably elegant feel that is non-oily or non-greasy when applied to the skin (Col. 2, Ins. 13-23, 39-43; Col. 3, Ins. 45-56; Col. 4, Ins. 56-58; Col. 5, Ins. 4-12), one of ordinary skill in the art would be motivated to manufacture the oil-in-water emulsion of Stroud *et al.* with individual emulsion droplets having a uniform diameter of about 1-10 μm (e.g. 1,000 to 10,000 nm), with the reasonable expectation that the resulting emulsion will successfully exhibit greater stability and impart an elegant feel when applied and worn on the skin.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

(10) Response to Argument (2a-2e)

Appellants' arguments have been addressed in the order in which they have been presented in the Appellants' Appeal Brief, in Section VII B, subsections 2a-2e, pp. 6-14.

Appellants' arguments have been fully considered, but are not found persuasive.

Appellants assert that "*STROUD is extremely broad and encompasses, for example, compositions comprising, inter alia, from about 0.5 % to about 20.0 % by weight of a self-tanning skin coloring agent subject to chemical instability (which is preferably dihydroxyacetone) and from about 0.1 % to about 15.0% by weight of a polyol*"; but, despite what may be explicitly disclosed in STROUD, that "*the actual teaching thereof is much narrower. In particular, while STROUD focuses on dihydroxyacetone as the self-tanning skin coloring agent subject to chemical instability, STROUD lists almost 20 suitable examples of polyols...most preferably sorbitol*", and

moreover that "*Sorbitol also is the only polyol that is employed in the exemplified compositions of STROUD...in a concentration of from 1.00 % to 5.00 % by weight*".

The Examiner, however, would like to point out, contrary to Appellants' assertion, that the actual teaching of STROUD really is compositions comprising about 0.5 % to about 20.0 % (preferably about 4.0 % to 6.0 %) by weight of a self-tanning skin coloring agent subject to chemical instability, preferably dihydroxyacetone, and from about 0.1 % to about 15.0% (preferably about 0.2 % to 10.0 %) by weight of a polyol. Of the many hundreds to thousands of known polyol compounds, STROUD discloses that the group of preferred polyols is limited to just 18 members, among which is glycerin. According to MPEP § 2123, patents are relevant as prior art for all that they disclose or would have reasonably suggested to one having ordinary skill in the art (see *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968 and *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989)); and that disclosed examples and preferred embodiments do not constitute a teaching away from the broader disclosure or non-preferred embodiments (see *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Appellants' arguments are rooted entirely on limiting the scope of the STROUD disclosure merely to the specific examples and the *most preferred* embodiments while dismissing the relevant broader teachings. Even STROUD rebuts Appellants' position by cautioning that the specific examples presented therein are "*solely for the purpose of further illustrating the invention and is in no way intended to be, nor should it be construed to be a limitation of any sort on the scope or any of the essential or auxiliary features of the present invention*" (see

STROUD, Col. 30, Ins. 3-7). Thus, STROUD is relevant for all that they disclose or would have reasonably suggested to one having ordinary skill in the art; STROUD expressly teaches and makes obvious to one of ordinary skill in the art that their method of tanning human skin can be successfully employed with a composition that contains 4 % by weight dihydroxyacetone and 10 % by weight glycerin just as well as by employing a composition that contains 4 % by weight dihydroxyacetone and 5 % by weight sorbitol.

Appellants assert that “*according to STROUD the stabilizing action of a polyol such as sorbitol on dihydroxyacetone is due to the formation of a cyclic ketal structure.* See, e.g., col. 27, line 7 to col. 28, line 44 of STROUD in this regard. Since the molecular weight of glycerin is about half the molecular weight of sorbitol it is reasonable to assume that only about 50 % of the amount of glycerin are needed for affording the same stabilizing effect as sorbitol”.

Respectfully, however, the Examiner cannot agree. Appellants have cited no reference and provided no hard evidence of any kind to support their conjecture; and Appellants' conjecture is hereby afforded the weight of an opinion on the matter. STROUD makes it clear that the whole notion of cyclic ketal structure formation is *only a theory* (see STROUD, Col. 27, Ins. 12-15). From a close inspection of STROUD, it would seem that, according to the theory, stabilization of dihydroxyacetone by cyclic ketal structure formation occurs by the reaction of the ketone group of dihydroxyacetone with a pair of vicinal hydroxyl groups on the polyol compound, and that a single polyol compound that has two (or more) pairs of vicinal hydroxyl groups in its structure can react with, and thus stabilize, two (or more) dihydroxyacetone molecules (see STROUD,

Col. 27, Ins. 25-35; Col. 28, Ins. 45-63). It is well known in the art that glycerin has three hydroxyl groups in its structure. Thus, contrary to other preferred polyol compounds disclosed by STROUD, a single glycerin molecule could react with, and thus stabilize, only one dihydroxyacetone molecule (i.e. not two or more). Thus, for this reason, contrary to Appellants' conjecture, it would seem that when using glycerin as the polyol compound, it should be present in an amount of at least twice the level of sorbitol or mannitol, not half the level. Specifically, if dihydroxyacetone comprises 4-6 % by weight of the composition, one of ordinary skill in the art would be motivated to employ a glycerin concentration at the higher end of the preferred polyol concentration range (for example, about 8-10 % by weight) to maximize the number of dihydroxyacetone molecules stabilized by cyclic ketal structure formation.

Appellants assert it is not seen that c) "*STROUD provides an apparent reason for one of ordinary skill in the art to employ glycerin in a concentration of more than 8 % by weight*"; and, moreover, that d), e) "*one of ordinary skill in the art would be prompted by STROUD to employ a ratio of dihydroxyacetone and glycerin which is smaller than 1:1, let alone smaller than 1:1.5*".

The Examiner, however, would like to point out that STROUD provides a reason for one of ordinary skill in the art to employ glycerin in a concentration of more than 8 % by weight by disclosing the following: *i*) that a polyol compound, used to stabilize dihydroxyacetone, the active agent, is an essential component of their composition; *ii*) that glycerin is a preferred polyol compound; and *iii*) that the polyol compound is present in an amount preferably up to about 10 % by weight of the composition. Moreover, as

noted *supra*, a single glycerin molecule could react with, and thus stabilize, only one dihydroxyacetone molecule (i.e. not two or more). Thus, if dihydroxyacetone is present at the preferred amount of 4-6 % by weight of the composition, one of ordinary skill in the art would be motivated to employ a glycerin concentration at the higher end of the preferred polyol concentration range (about 8-10 % by weight), such that the dihydroxyacetone: glycerin ratio is smaller than 1:1, and better yet smaller than 1:1.5, to maximize the chances that each and every dihydroxyacetone molecule will encounter and react with a glycerin molecule to become stabilized by cyclic ketal structure formation.

Therefore, in view of the fact patterns of the instant case, and the grounds of rejection outlined by the Examiner, Appellants' arguments are not compelling and do not overcome the rejections of record.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Conferees:

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